

REMARKS

Reconsideration of the present application is respectfully requested for the reasons that follow.

Specification Amendment

The specification has been amended to insert a reference to the electronic form of the sequence listing being filed concurrently herewith. It is submitted that this amendment does not constitute new matter, and its entry is requested.

Claim Amendments

Claims 22 has been amended to remove the claim limitation relating to the short peptide linker. Claim 22 has also been amended to specify that the fusion protein comprises chains identified by specific SEQ ID NOs, incorporating the limitations of claims 29-30 which provide written description support for these amendments. Claim 22 has further been amended to specify that the chains include variants of the amino acid sequences set forth in the specific SEQ ID NOs. There is written description support for these amendments in the claims as filed and in the specification as filed at least at p. 2, ll. 18-23, p. 4, ll. 14-19 and 29-31 and Figure 1. No new matter is added.

Claims 24-27, 29, 30 and 41 have been canceled in view of the amendments to claim 22.

Claim 32 has been canceled in favor of new claim 45.

New claims 42-45 have been added to more specifically describe the structure of the fusion product, and new claims 46-47 have been added to claim a pharmaceutical composition and kit based on new claim 45. There is written description support for these amendments in the specification as filed at least at Figure 1. No new matter is added.

Submission of Substitute Sequence Listing

An electronic form of a substitute sequence listing has also been provided to correct the sequence in SEQ ID NO:4 to contain a single Cys residue at position 137

instead of the two Cys residues at positions 137 and 138 in order to conform to the sequence shown in Figure 1. It is submitted that the correction of SEQ ID NO:4 does not constitute new matter, and entry of the electronic form of the substitute sequence listing is requested.

Rejections under 35 USC § 112, first paragraph

The Examiner has rejected claims 22-33 and 37-38 under 35 USC § 112, first paragraph, for lack of enablement. Specifically, the Examiner argues that the specification is enabling for the fusion proteins of SEQ ID NO: 4 and SEQ ID NO: 35, but does not provide reasonable enablement for many of the remaining claim limitations. The Examiner argues that undue experimentation would be required to practice the claimed invention because the specification lacks sufficient guidance on how to make the claimed genus of fusion proteins, and their fragments, homologues and related proteins with various substitutions, deletions or additions.

The Examiner has additionally rejected these same claims under 35 USC § 112, first paragraph, for lacking written description, although the Examiner concedes that the specification does provide written description support for the fusion proteins of SEQ ID NO: 4 and SEQ ID NO: 35. Specifically, the Examiner argues that one of skill in the art cannot contemplate all of the fusion protein, composition and kit possibilities recited in the claims because a representative description of the structural and functional properties of the claimed subject matter is lacking from the specification.

Applicants traverse both rejections. Applicants disagree with the Examiner's interpretation of the claims. However, solely in the interest of expediting prosecution, Applicants have amended independent claim 22, as discussed above to include additional structural limitations in the fusion protein and to specify specific variants. Specifically, each of the fusion protein chains is identified by their respective SEQ ID NO, and the variants are identified with reference to the respective SEQ ID NO. As such, amended claim 22 is now directed to a fusion protein which has identifying structural features. In addition, one of skill in the art would be able to make and use the claimed fusion proteins based on the representative analysis demonstrated in the

examples. Accordingly, Applicants submit that the specification fully enables the claimed subject matter and provides a written description of the claimed subject matter as required by 35 USC § 112, first paragraph. Withdrawal of these rejections is requested.

Rejections under 35 USC § 103(a)

The Examiner has rejected claims 22-27 and 29-32 under 35 USC § 103(a) as being obvious over Vailes (J. Allergy Clin. Immunol., November 2002, 110(5), pp. 757-762) in view of George (Protein Engineering, 15(11), pp. 871-879, 2003). Vailes is directed to the production of recombinant cat allergen Fel d 1, which is a heterodimer of chain 1 and chain 2, in the baculovirus expression system. George is directed to an analysis of protein domain linkers, used to create multifunctional chimeric proteins. The Examiner argues that Vailes teaches all of the limitations of these rejected claims, except for the linker. However, as to the carbon-nitrogen linker, the Examiner argues that this is inherent in any amide bond. Additionally, as to the peptide linker of 1 to 9 amino acids, the Examiner argues that George teaches such small linkers and that it would be obvious to one of ordinary skill in the art to add the linkers taught in George to the recombinant Fel d 1 of Vailes to arrive at the presently claimed subject matter. Applicants traverse.

Applicants disagree with the Examiner's interpretation of the claims, however, solely in the interest of expediting prosecution, independent claim 22 has been amended, as discussed above, to remove the limitation relating to the peptide linker. Thus, the obviousness rejection is rendered moot as to that limitation. Accordingly, independent claim 22 is now directed to a fusion protein wherein the two chains are joined by carbon-nitrogen linker, i.e., they are in peptide linkage as shown in Figure 1. In addition, the claimed fusion protein is now identified by specific SEQ ID NOs and is arranged in a specific orientation. Vailes does not disclose the fusion protein comprising the two amino acid chains identified by SEQ ID NOs 1 and 2. George does not cure this deficiency. Accordingly, Applicants submit that the combination of Vailes and George

does not render the claimed subject matter obvious. Withdrawal of this rejection is requested.

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By /Carolyn L. Greene/
Carolyn L. Greene
Attorney for Applicant
Registration No. 57,784
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040